AUG 1 4 2000

K001572

II. 510(k) Summary as required by 807.95 (c)
SUMMARY AND CERTIFICATION
Summary of Safety & Effectiveness Information

II. 1. Proprietary Device Name

Neolus Needle

II.2. Classification Name

Hypodermic Single Lumen Needle

II.3. Reason for Submission

New Device

II.4. Intended Use

The Neolus Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

II.5. Description

The Neolus Needle is a sterile Hypodermic Single Lumen Needle for single use, consisting of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene designed to be connected with a male connector (nozzle) of a piston syringe or an intra-vascular administration set.

II.6. Substantial Equivalence

The Neolus Needle submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Disposable Hypodermic Needle which is the subject of K771203. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

INTENDED USE:	Both needles being Hypodermic Single Lumen Needles, are sterile medical devices for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
DESIGN AND MATERIALS:	Both needles are made of a stainless steel needle tube that is sharpened at one end and at the other end joined to a female connector (6% luer) made of polypropylene. Both needles are packed in a blister pack (paper – film).

Note: Because of market preferences, TMC does not manufacture a short bevel needle currently, however a short bevel is covered under K771203.

The differences between both needles :

- The Neolus Needles are sterilized by ethylene oxide gas while Terumo Disposable Hypodermic Needles are sterilized by gamma-irradiation.
- The Neolus Needles cover a wider range of items regarding external diameter (a 24 G needle is available), needle length (apart from 12, 25, 30 and 40 mm also Neolus Needles with a needle length of 16, 20, 23, 50 and 70 mm are available).

The above mentioned differences do not affect the substantial equivalence of the devices.

Neolus Needles

Proposed:

PRODUCT CODE	NEEDLE ⌀ (Gauge & mm)	NEEDLE LENGTH (inch & mm)	WALL THICKNESS	NEEDLE BEVEL
NN-1838RVS	18 G – 1.2 mm	1 ½" – 40 mm	Thin Wall	Regular bevel
NN-1838SVS	18 G – 1.2 mm	1 ½" – 40 mm	Thin Wall	Short bevel
NN-1850RVS	18 G – 1.2 mm	2" – 50 mm	Regular Wall	Regular bevel
NN-1925RVS	19 G – 1.1 mm	1" – 25 mm	Thin Wall	Regular bevel
NN-1938RVS	19 G – 1.1 mm	1 ½" – 40 mm	Thin Wall	Regular bevel
NN-1938SVS	19 G – 1.1 mm	1 ½" – 40 mm	Thin Wall	Short bevel
NN-1950RVS	19 G – 1.1 mm	2" – 50 mm	Regular Wall	Regular bevel
NN-2025RVS	20 G – 0.9 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
NN-2038RVS	20 G – 0.9 mm	1 ½" – 40 mm	Ultra Thin Wall	Regular bevel
NN-2038SVS	20 G – 0.9 mm	1 ½" – 40 mm	Ultra Thin Wall	Short bevel
NN-2050RVS	20 G – 0.9 mm	2" – 50 mm	Regular Wall	Regular bevel
NN-2070SVS	20 G – 0.9 mm	2 ¾" – 70 mm	Regular Wall	Short bevel
NN-2116RVS	21G – 0.8 mm	5/8" – 16 mm	Regular Wall	Regular bevel
NN-2125RVS	21 G – 0.8 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
NN-2138RVS	21 G – 0.8 mm	1 ½" – 40 mm	Ultra Thin Wall	Regular bevel
NN-2138SVS	21 G – 0.8 mm	1 ½" – 40 mm	Ultra Thin Wall	Short bevel
NN-2150RVS	21 G – 0.8 mm	2" – 50 mm	Regular Wall	Regular bevel
NN-2232RVS	22 G – 0.7 mm	1 ¼" – 30 mm	Ultra Thin Wall	Regular bevel
NN-2232SVS	22 G – 0.7 mm	1 ¼" – 30 mm	Ultra Thin Wall	Short bevel
NN-2238RVS	22 G – 0.7 mm	1 ½" – 40 mm	Ultra Thin Wall	Regular bevel
NN-2250RVS	22 G – 0.7 mm	2" – 50 mm	Regular Wall	Regular bevel
NN-2316RVS	23 G – 0.6 mm	5/8" – 16 mm	Ultra Thin Wall	Regular bevel
NN-2325RVS	23 G – 0.6 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
NN-2332RVS	23 G – 0.6 mm	1 ¼" – 30 mm	Ultra Thin Wall	Regular bevel
NN-2425RVS	24 G – 0.55 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel

PRODUCT CODE	NEEDLE ∅ (Gauge & mm)	NEEDLE LENGTH (inch & mm)	WALL THICKNESS	NEEDLE BEVEL
NN-2516RVS	25 G – 0.5 mm	5/8" – 16 mm	Ultra Thin Wall	Regular bevel
NN-2525RVS	25 G – 0.5 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
NN-2613RVS	26 G – 0.45 mm	½" – 12 mm	Regular Wall	Regular bevel
NN-2623RVS	26 G – 0.45 mm	23 mm	Regular Wall	Regular bevel
NN-2719RVS	27 G – 0.4 mm	¾" – 20 mm	Regular Wall	Regular bevel

Terumo Disposable Hypodermic Needles

Predicate:

PRODUCT CODE	NEEDLE ∅ (Gauge & mm)	NEEDLE LENGTH (inch & mm)	WALL THICKNESS	NEEDLE BEVEL
3NN*1838R	18 G – 1.2 mm	1 ½" – 40 mm	Thin Wall	Regular bevel
3NN*1925R	19 G – 1.1 mm	1" – 25 mm	Thin Wall	Regular bevel
3NN*1938R	19 G – 1.1 mm	1 ½" – 40 mm	Thin Wall	Regular bevel
3NN*2025R	20 G – 0.9 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
3NN*2038R	20 G – 0.9 mm	1 ½" – 40 mm	Ultra Thin Wall	Regular bevel
3NN*2125R	21 G – 0.8 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
3NN*2138R	21 G – 0.8 mm	1 ½" – 40 mm	Ultra Thin Wall	Regular bevel
3NN*2232R	22 G – 0.7 mm	1 ¼" – 30 mm	Ultra Thin Wall	Regular bevel
3NN*2238R	22 G – 0.7 mm	1 ½" – 40 mm	Ultra Thin Wall	Regular bevel
3NN*2325R	23 G – 0.6 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
3NN*2525R	25 G – 0.5 mm	1" – 25 mm	Ultra Thin Wall	Regular bevel
3NN*2613R	26 G – 0.45 mm	½" – 12 mm	Regular Wall	Regular bevel
3NN*2713R	27 G – 0.4 mm	½" – 12 mm	Regular Wall	Regular bevel

Materials:

COMPONENT	NEOLUS NEEDLE (Proposed)	TERUMO DISPOSABLE HYPODERMIC NEEDLE (Predicate)
Cannula	Stainless steel	Stainless steel
Hub	Polypropylene	Polypropylene
Glue	Epoxy glue	Epoxy glue
Lubricant	Silicone	Silicone

PRINCIPLES OF OPERATION/ TECHNOLOGY STATEMENT:	The Neolus Needles and the Terumo Disposable Hypodermic Needles are both operated manually.
COMPARISON TESTING OF NEOLUS NEEDLES WITH EN ISO 7864:	The Neolus Needles comply with the requirements specified in EN ISO 7864 (1995): Sterile Hypodermic Needles for single use (= ISO 7864: 1993) with exception of: Section 9.1: Conical fitting: if the hub has a locking fitting, it shall be in accordance with ISO 594-2. The Neolus Needles are not completely matching the specification of ISO 594-2. The dimension specified as the outside diameter across the lugs of the hub is not in compliance, however when tested in accordance to ISO 594-2, no liquid or air leakage is observed. Section 13.2.a: Patency of lumen: no specifications are given for a 24 G and a 25 G having an ultra thin wall cannula. Consequently the 24 G and the 25G Neolus Needles having an ultra thin wall cannula could not be compared with a reference for this property. Section 13.2.b: The flow rates for the different items of the Neolus Needles are not available.

II. 7. Additional Safety Information

The sterility of the Neolus Needles is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556: "Sterilization of Medical Devices: Requirements for medical devices to be labelled STERILE".

The bio-compatibility of the Neolus Needles is tested in accordance with the tests recommended in the FDA General Program Memorandum # G95-1 (5/1/95): Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" [External Communicating Devices, Blood Path Indirect, Limited Duration of Contact (L 24 hours)]. The blood contacting materials were found to be compatible.

A LAL test is performed on production samples of each lot number.

The manufacturing control test methods include controls on functional performance.

The expiration dating for the Neolus Needles has been established at 60 months or five (5) years.

II.8. Conclusion

The Neolus Needle submitted in this 510(k) file is substantially equivalent in intended use, design, specifications, technology/principles of operations, materials and performance to the cleared Terumo Disposable Hypodermic Needle which is the subject of K771203.
Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

II.9. Preparation info

Date prepared:	05/2000
Prepared by:	Mrs. M.J. Aerts - Manager Regulatory Affairs
Prepared for:	TERUMO EUROPE N.V.
	Researchpark Zone 2, Interleuvenlaan 40, 3001 Leuven BELGIUM
Tel.:	0032 / 16 / 381 353

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2000

Ms. M.J. Aerts
Manager, Regulatory Affairs
Terumo Europe N.V.
Researchpark Zone 2
Interleuvenlaan 40
Leuven 3001,
BELGIUM

Re: K001572
Trade Name: Neolus Needle
Regulatory Class: II
Product Code: FMI
Dated: May 19, 2000
Received: May 22, 2000

Dear Ms. Aerts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001572

Device Name: NEOLUS NEEDLE (= Hypodermic Needle)

Indications For Use:

The NEOLUS NEEDLE being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Catherine Cucinotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001572

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Fomat 1-2-96)